IN THE UNITED STATES DISTRICT COURT

DISTRICT OF NEW MEXICO

HOSPICE OF NEW MEXICO, LLC, a New Mexico Corporation, Plaintiff, v. KATHLEEN SEBELIUS,[1] Secretary of United States Department of Health and Human Services, Defendant.	)	Case No. 1:09-CV-00145 **Oral Argument Requested**

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT/STAY AND BRIEF IN SUPPORT THEREOF

COMES NOW plaintiff, Hospice of New Mexico, LLC ("Hospice of New Mexico") and, pursuant to Rules 56 and 65 of the Federal Rules of Civil Procedure, and pursuant to Chief Magistrate Judge Lorenzo F. Garcia's Order and Briefing Schedule RE Cross-Motions for Summary Judgment (filed 8/10/09), moves for: (a) summary judgment on its claim for declaratory relief that the hospice cap regulation found at 42 C.F.R. § 418.309(b)(1) is invalid as contrary to the express statutory mandate codified at 42 U.S.C. § 1395f(i)(2)(C); and (b) pending determination of the motion and/or after determination of the motion and pending entry of

[1] Per FED. R. CIV. P. 25(d) Kathleen Sebelius, the new HHS Secretary, is automatically substituted in as successor to Interim Secretary Charles Johnson.

suitable judgment, suspension by this Court of the FY 2007 cap repayment demand to Hospice of New Mexico.

In support of Hospice of New Mexico's Motion for Summary Judgment, it relies on the undisputed material facts set forth below together with the argument and authorities following thereafter.

I. INTRODUCTION

By this motion, Hospice of New Mexico seeks summary judgment as to the invalidity of HHS' hospice cap regulation found at 42 C.F.R. § 418.309(b)(1), on the grounds that the regulation is facially invalid as inconsistent with the authorizing statute. Moreover, Hospice of New Mexico seeks suspension of the recent FY 2007 repayment demand made by HHS to Hospice of New Mexico, pending either determination of this motion and/or final judgment in this case. Because the hospice cap requires somewhat complex analysis, Hospice of New Mexico also requests that this Court consider setting oral argument to clarify the issues in dispute.

Hospice of New Mexico is a Medicare certified hospice provider based in Albuquerque, New Mexico. As a hospice provider, Hospice of New Mexico provides hospice services to eligible Medicare patients, namely patients who are terminally ill and who have been certified by physicians to have less than a six month life expectancy.

The Federal government pays hospice providers, like Hospice of New Mexico, pursuant to a Medicare program established under Title XVIII of the Social Security Act (the "Medicare Act"). The Department of Health and Human Services ("HHS") administers the hospice benefit and reimburses hospices on a per diem basis for services provided to Medicare beneficiaries.

But, total annual payments to hospices are subject to an aggregate annual provider cap (the "cap"), calculated as the product of a per patient fixed allowance (adjusted up annually for inflation) for such year hospice services were provided multiplied by the "number of beneficiaries" served in such year. Any provider whose annual revenues from Medicare exceed its aggregate cap is subject to a demand from HHS for repayment of the difference.

In the Medicare Act, Congress directed HHS to make a proportional allocation of each beneficiary's cap allowance across years of service. Specifically, Congress mandated that the "number of beneficiaries" counted in any given year for cap purposes must be "reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year." See 42 U.S.C. § 1395f(i)(2)(C). The statute contemplates what in fact regularly occurs: patients in some cases are on hospice service across two or sometimes more years of service. To be fair, Congress required HHS to make a proportional allocation of each such patient's cap allowance across such years of service.

In promulgating a regulation to calculate the annual aggregate allowance for hospices, HHS acknowledged this Congressional directive, but nonetheless proposed what it conceded was a "different" regulation, one that would count each beneficiary only in the "initial year … rather than attempt to perform a proportional adjustment." See 48 F.R. 38,146 at 38,158 (emphasis added); 42 C.F.R. § 418.309(b)(1). In short, HHS admitted that it would not make the required proportional adjustment.

Hospice of New Mexico has been subject to demands for repayment under the cap from HHS in the amounts of $793,934 and $1,010,593 for the fiscal years ended October 31, 2006 and October 31, 2007, respectively. Hospice of New Mexico believes that the failure to make a

proportional allocation of its patients' cap allowances has resulted in a mismatch of cap allowance and revenue, resulting in overstated demands. Hospice of New Mexico timely appealed both demands and obtained leave to seek judicial review of the validity of the regulation used to calculate the demands.

The regulation by which HHS calculates the aggregate cap amount, 42 C.F.R. § 418.309(b)(1), is directly contrary to Congress' express directive to make a proportional allocation of each beneficiary's cap allowance as required by 42 U.S.C. § 1395f(i)(2)(C). On this basis, under the terms of the Administrative Procedure Act, Hospice of New Mexico is entitled to summary judgment that the cap regulation, 42 C.F.R. § 418.309(b)(1), is invalid. 5 U.S.C. § 706(2)(A) and (C). Hospice of New Mexico is also entitled to orders setting aside prior cap calculations made pursuant to the invalid regulation. Indeed, two other district courts have already held the regulation invalid; and, in the most recent case in the Central District of California, the Court set aside, and enjoined prospective application of, the regulation. (UF 24, 25.)

II. UNDISPUTED MATERIAL FACTS

A. The Hospice Benefit And Cap

1. In 1982, Congress created the hospice benefit to provide end-of-life care to terminally ill patents. In devising this benefit, Congress imposed two limits: (a) hospice care for any given patient was originally limited to a maximum of 210 days; and (b) total payments to a given hospice annually could not exceed that hospice's aggregate cap allowance. In 1990, Congress removed the individual patient limitation. Now, an individual patient may remain in hospice care for an unlimited number of days provided such patient remains certified as

terminally ill with a life expectancy of six months or less. (42 U.S.C. § 1395d(a)(4) and (d)(1) (unlimited individual stay), including Historic and Statutory Notes, 1990 Amendments, Pub.L. 101-508, § 4006(a) (removing 210 day limit), attached to RJN at sequential pp. 4-5 (Ex. 1); and 42 U.S.C. § 1395f(i)(2) (aggregate cap), attached to RJN at p. 30 (Ex. 6).)

2. However, Congress has not yet changed the second limit, namely that the total payments to a hospice provider in any fiscal year may not exceed an aggregate cap, calculated as the product of the individual cap allowance (adjusted annually for inflation) and the "number of Medicare beneficiaries" in a given accounting year. (Id.)

3. The Medicare Act specifically provides that the "number of beneficiaries" in an accounting year for cap purposes must be adjusted to reflect the time each such individual was provided hospice care in a previous or subsequent accounting year:

> "For the purposes of subparagraph (A), the 'number of Medicare beneficiaries' in a hospice program in an accounting year is equal to the number of individuals who have made an election under subsection (d) of this section with respect to the hospice program and have been provided hospice care by (or under arrangements made by) the hospice program under this part in the accounting year, such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year or under a plan of care established by another hospice program." (Emphasis added.)

(42 U.S.C. § 1395f(i)(2)(C), attached to RJN at p. 30 (Ex. 6).)

B. The Regulation At Issue

4. In 1983, when HHS issued its proposed regulation to implement the hospice cap, it acknowledged that Congress had instructed it to perform a proportional allocation:

> "The statute specifies that the number of Medicare patients used in the calculation is to be adjusted to reflect the portion of care provided in a previous or subsequent reporting year or in another hospice."

(48 F.R. 38,146 at 38,158 (Aug. 22, 1983), attached to RJN at p. 32 (Ex. 7).)

5. However, HHS admitted that it was not going to adopt a regulation consistent with Congress' express mandate, instead choosing to give providers credit for the cap only in the **initial** year of service, regardless whether the patient remained on service in a later accounting year:

> "With respect to the adjustment necessary to account for situations in which a beneficiary's election overlaps two accounting periods, we are proposing to count each beneficiary only in the reporting year in which the preponderance of the hospice care would be expected to be furnished **rather than attempt to perform a proportional adjustment**." (Emphasis added.)

(Id.)

6. In so doing, HHS conceded that it was planning not to implement the plain language of the statute because it would be "difficult":

> "Although section 1814(i)(2)(C) of the Act specifies that the cap amount is to be adjusted 'to reflect the proportion of the hospice care that each such individual was provided in a previous or subsequent accounting year . . .' such an adjustment would be difficult in that the proportion of the hospice stay occurring in any given year would not be known until the patient dies or exhausted his or her hospice benefits. We believe the proposed alternative of counting the beneficiary in the reporting period where the beneficiary used most of the days of covered hospice care will achieve the intent of the statute without being burdensome." (Emphasis added.)

(Id.)

7. Notably, however, when it came to implementing the companion statutory requirement that the cap be apportioned among different hospices if two or more hospices provided services to a specific patient, HHS did require such proportional calculations:

> "When a beneficiary elects to receive hospice benefits from two different hospices, we are proposing a proportional application of the cap amount."

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> "We are aware that this type of apportioning of the beneficiary's stay may result in the inclusion of a beneficiary in the calculation of the cap for a reporting period other than the period for which the services were furnished, since it is necessary that the beneficiary die or exhaust his or her benefits before the percentage can be determined. However, we believe that this proposal is the most equitable means of implementing the statutory directive to adjust the cap amount to reflect the proportion of care furnished under a plan of care established by another hospice program." (Emphasis added.)

(Id.)

8. In December 1983, HHS issued its final hospice reimbursement regulations, including the provision allocating the hospice cap amount for a beneficiary only in the initial year in which the patient elected hospice care. The regulation provides:

> "Each hospice's cap amount is calculated by the intermediary by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries who elected to receive hospice care from that hospice during the cap period. For purposes of this calculation, the number of Medicare beneficiaries includes –
>
> (1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care, in accordance with § 418.24 from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).
>
> (2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represent the portion of a patient's total stay in all hospices that was spent in that hospice. . . " (Emphasis added.)

(42 C.F.R. § 418.309(b)(1) and (2), attached to RJN at p. 34 (Ex. 8).)

9. HHS' reporting year for hospices runs from November 1 to October 31 of each year. (42 C.F.R. § 418.309(a), attached to RJN at p. 34 (Ex 8).)

10. Importantly, HHS recognized that its method of limiting cap allocation to a single year per patient would be prejudicial to hospices who provided a few days of care in one year

with the majority of care in the next year. In an attempt to ameliorate this prejudice, HHS advanced the "initial year" cap calendar 35 days earlier, based on its assumption that the average length of stay in hospice care would be 70 days. (48 C.F.R. § 56,008, attached to RJN at pp. 40-41 (Ex 10).) Under HHS' revised cap year, if a patient's care started on or after September 28, that patient's full cap allowance would be pushed into the second year of care, not the first year of care. (42 C.F.R. § 418.309(b)(1), attached to RJN at p. 34 (Ex. 8).)

11. Notably, HHS' advancement of the initial year cap calendar by 35 days (with a 70 day length of stay) in December of 1983 was a revision of an earlier attempt in August of 1983 to estimate the average length of stay at 44 days. (48 F.R. 38,146 at 38,158, attached to RJN at p. 32 (Ex. 7).)

12. In calendar year 2005, hospices across 15 states had average lengths of stay in hospices in excess of 70 days, including New Mexico (101 days). (See Exhibit A to Declaration of David Daucher, filed in Sojourn Care, Inc. dba Sojourn Care of Tulsa v. Michael O. Leavitt, Case No. 07-CV-375-GKF-PJC (N.D.Ok. filed 2007), attached to RJN at pp. 10-11 (Ex. 2).)

13. Over fiscal years 2006 and 2007, Hospice of New Mexico's average length of stay was 193 days. (Conrad Decl,, ¶¶ 8-9.)

14. The statute expressly permits an unlimited number of days of hospice care for each eligible individual. (42 U.S.C. § 1395d(a)(4) and (d)(1), attached to RJN at pp. 4-5 (Ex. 1.)

C. Hospice Of New Mexico And The History Behind This Lawsuit

15. Hospice of New Mexico is a Medicare certified hospice provider based in Albuquerque, New Mexico. Hospice of New Mexico received its license as a hospice provider

in July 2004. Since that time, Hospice of New Mexico has served more than 1,000 patients in Albuquerque, the vast majority of whom are now deceased. (Conrad Decl., ¶ 2.)

16. In its first fiscal year (July 2004 through October 31, 2005) Hospice of New Mexico had a significant cap surplus, in excess of $700,000, meaning that Hospice of New Mexico cap allowances for that year exceeded Medicare revenue for the same period by that amount. As a result, HHS did not make any demand for repayment for the 2005 fiscal year. (Conrad Decl., ¶ 3, Ex. A (CMS Letter showing surplus).) Such surpluses may not be carried forward to subsequent years, but are instead trapped in such prior year and unavailable to offset revenue in subsequent years.

17. But, in fiscal year 2006 (November 1, 2005 - October 31, 2006), Hospice of New Mexico continued to serve many patients first admitted in fiscal year 2005. Medicare paid Hospice of New Mexico for these services as rendered in fiscal year 2006. However, because the cap regulation allocates the entire allowance to the first year, in many cases, Hospice of New Mexico received no cap allocation for these patients in fiscal year 2006. (Conrad Decl., ¶ 4.)

18. As a result, on April 22, 2008, Medicare sent Hospice of New Mexico a demand for repayment of $793,934 for exceeding its fiscal year 2006 cap. If Medicare had followed the Congressional mandate to allocate cap room across years of service, Hospice of New Mexico believes that its cap liability for fiscal year 2006 and future years would have been, on net, materially reduced. As a result, Hospice of New Mexico has suffered material prejudice from Medicare's failure to follow the Congressionally-mandated proportional allocation of cap allowances across years of service. (Conrad Decl., ¶ 5, Ex. B (2006 demand letters).) Indeed,

Hospice of New Mexico has already repaid the FY 2006 demand in full (without prejudice to the objections contained herein). (Conrad Decl., ¶ 6.)

19. On October 16, 2008, Hospice of New Mexico timely filed an appeal of the FY 2006 cap determination with the Provider Reimbursement Review Board ("PRRB"), challenging the validity of the Federal regulation pursuant to which the cap was calculated. Because it appeared that the PRRB lacked jurisdiction to assess the validity of a regulation, on November 25, 2008, Hospice of New Mexico applied for leave to seek expedited judicial review of its appeal. On December 16, 2008, the PRRB granted Hospice of New Mexico's expedited judicial review request, finding that there are no material facts in dispute, that the amount in controversy exceeds $10,000, and that Hospice of New Mexico's appeal involves principally a legal challenge to the validity of the regulation. (Conrad Decl., ¶ 7, Ex. D.) When the PRRB makes such a ruling, a Medicare provider has 60 days to file a civil action in Federal District Court. (42 U.S.C. §1395oo(f)(1), attached to RJN at pp. 36-37 (Ex. 9).) Hospice of New Mexico timely filed its original complaint in this matter on February 13, 2009.

20. Similarly, in fiscal year 2007 (November 1, 2006 - October 31, 2007), Hospice of New Mexico continued to serve many patients first admitted in fiscal year 2006 and a few patients first admitted in fiscal year 2005. Medicare paid Hospice of New Mexico for these services as rendered in fiscal year 2007. However, because of the cap regulation which allocates the entire allowance to the first year, Hospice of New Mexico received no cap allocation for these patients in fiscal year 2007. (Conrad Decl., ¶¶ 4-5.)

21. As a result, on May 27, 2009, Medicare sent Hospice of New Mexico a demand for repayment of $1,010,593.00 for exceeding its fiscal year 2007 cap. If Medicare had followed

the Congressional mandate to allocate cap room across years of service, Hospice of New Mexico believes that its cap liability for fiscal year 2007 and future years, on net, would have been materially reduced. As a result, Hospice of New Mexico has suffered material prejudice from Medicare's failure to follow the Congressional mandated allocation of cap allowances across years of service. (Conrad Decl., ¶¶ 4-5, Ex. C (2007 demand letter).)

22. On July 14, 2009, Hospice of New Mexico timely filed an appeal of the FY 2007 cap determination with the PRRB, challenging the validity of the Federal regulation pursuant to which the cap was calculated. Concurrently, Hospice of New Mexico sought expedited judicial review of its appeal. On July 24, 2009, the PRRB again granted Hospice of New Mexico's expedited judicial review request, finding that there are no material facts in dispute, that the amount in controversy exceeds $10,000, and that Hospice of New Mexico's appeal involves principally a legal challenge to the validity of the regulation. (Conrad Decl., ¶ 7, Ex. E.) Hospice of New Mexico has amended its original complaint, by unopposed motion, to include this second claim related to FY 2007.

23. Hospice of New Mexico has not fully repaid the FY 2007 demand but has instead applied for an extended repayment plan as to that amount and is paying the sum of $22,098.95 per month, inclusive of interest at approximately 11% interest pending final approval of that repayment plan. (Conrad Decl., ¶ 6.)

D. Prior District Courts Have Found The Same Regulation Invalid

24. A district court in the Northern District of Oklahoma has previously addressed the question of 42 C.F.R. § 418.309(b)(1)'s validity. (See Sojourn Care, Inc. dba Sojourn Care of Tulsa v. Michael O. Leavitt, Case No. 07-CV-375-GKF-PJC (N.D.Ok. filed 2007).)

Specifically, the Sojourn Care court made the following findings on the record about the HHS regulation governing calculation of the cap (42 C.F.R. § 418.309(b)), before granting summary judgment that the regulation was invalid:

> "[W]ith due respect I agree with the plaintiffs here that the regulation as written does not comport or comply with the statute … I don't believe that the statutory language which requires that the number of Medicare beneficiaries is to be reduced is in any way reflected in an allocation to one of the fiscal years, one or the other, and it's certainly not – it doesn't honor the statutory language that the number must be reduced to reflect the proportion of hospice care that each such individual was provided … The number of Medicare beneficiaries is simply not reduced under this regulation in any way to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent reporting year … I simply don't believe that it follows the statutory mandate in the statute." (Emphasis added.)

(See transcript to Sojourn Care hearing on motion for summary judgment, attached to RJN at pp. 13-14 (Ex. 3).)

25. Similarly, a district court in the Central District of California more recently held the same regulation, 42 C.F.R. § 418.309(b)(1), invalid and also set it aside and enjoined prospective application. (See Los Angeles Haven Hospice, Inc. v. Michael O. Leavitt, Case No. 08-4469-GW (RZx) (C.D.Cal. filed 2008).) Specifically, the Haven Hospice court granted the plaintiff's motion for summary judgment, and held 42 C.F.R. § 418.309(b)(1) invalid. The Haven Hospice court did so after first ruling that the plaintiff had "Article III standing to challenge the regulation in question," based in part of the following findings:

> "The injury in fact in this context (if Plaintiff's statutory argument has merit) is the fact that HHS is operating an invalid regulation, leading to accounting and payment inaccuracies. Thus, the injury question here is not whether Plaintiff's liability is greater under the operation of section 418.309 than it would be under some other regulation. There is no regulation. That is always true when a party challenges an allegedly invalid regulation. [Citations omitted.]

> To require the plaintiff in such a circumstance to somehow devise their own proposed regulation which they believe comports with Congress's precise statutory directive would send the parties and the Court scurrying down the rabbit hole to Wonderland. If Defendant [HHS] is concerned about advisory opinions, it seems odd that it would require everyone involved –including the Court—to engage in such a speculative exercise. This understanding of the standing question as it relates to this case is consistent with the Supreme Court's guidance that where the plaintiff is itself an object of the government action (as is clearly the case here) "there is ordinarily little question that the action … has caused [it] injury, and that a judgment preventing or requiring the action will address it.' [Citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 561-562 (1992).]"

The Los Angeles Haven Hospice court then found 42 C.F.R. § 418.309(b)(1) invalid as contrary to express Congressional directives:

> "…Congress unquestionably required that the number of medicare beneficiaries be reduced to reflect 'the proportion' (not simply a proportion or an estimate, as Defendant [HHS] would apparently have 'reflect' mean in this context[2]) of hospice care that 'each such individual' (not individuals in the aggregate) 'was provided in a previous or subsequent accounting year.' [Citations omitted.] The regulation in question runs counter to that directive. [Citations omitted.] Congress has 'directly spoken' to this precise question. [Citing Chevron, U.S.A., Inc. v. NRDC, Inc, et al., 467 U.S. 837, 842 (1984).] 'That is the end of the matter.' [Id.]"

(See order granting plaintiff's motion for summary judgment and denying defendant's motion for summary judgment in Los Angeles Haven Hospice case, attached to RJN at pp. 20-24 (Ex. 4), emphasis in original.) At the same time as the Haven Hospice court granted summary judgment, it immediately suspended the FY 2006 cap repayment demand at issue in that case. (Id. at 1.)

On August 21, 2009, the Los Angeles Haven Hospice court entered a final judgment, including the following determinations:

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[2] Here, the Los Angeles Haven Hospice court included the following footnote: "When understood in conjunction with Congress's specific reference to 'the proportion,' Defendant's reading of 'reflect' is synonymous with 'distort.'" (See order granting plaintiff's motion for summary judgment and denying defendant's motion for summary judgment in Los Angeles Haven Hospice case, attached to Request for Judicial Notice as Exhibit 4.)

> "HHS' regulation governing calculation of the hospice cap, published at 42 C.F.R. 418.309(b)(1), is arbitrary and capricious and in excess of statutory authority for the reasons specified in this Court's prior order of July 13, 2009 granting summary judgment of invalidity. Therefore, pursuant to this Court's authority under 5 U.S.C. § 706(2)(A) & (C) of the Administrative Procedure Act, the hospice cap regulation at 42 C.F.R. 418.309(b)(1) is unlawful and set aside. HHS is hereby enjoined prospectively from using the current regulation found at 42 C.F.R. 418.309(b)(1) to calculate hospice cap liability for any hospice.
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> "HHS' prior calculation of Haven Hospice's cap liability for fiscal year 2006, including HHS' repayment demand of April 2, 2008, is hereby set aside. HHS is further ordered not later than one year from the date of this judgment to return prior payments by Haven Hospice on the 2006 demand, with interest; except that, at any time prior to such return, HHS may credit any portion of such prior payments, with interest, to a new cap repayment demand to Haven Hospice for 2006, such demand to be calculated in accordance with 42 U.S.C. § 1395f(i)(2)."

(See Final Judgment, Los Angeles Haven Hospice case, attached to RJN at pp. 25-26 (Ex. 5).) Although the Haven Hospice judgment gives prospective relief against further demands based upon the invalid regulation, it has no effect upon prior issued demands, such as the FY 2006 and 2007 demands at issue in this case.

Accordingly, Hospice of New Mexico has brought this action against HHS for a declaration that the cap regulation found at 42 C.F.R. § 418.309(b)(1) is invalid and that the specific prior cap repayment demands to Hospice of New Mexico be set aside.

III. STANDARD FOR SUMMARY JUDGMENT

A motion for summary judgment should be granted where there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. See FED.R.CIV.P. 56(c).

IV. ARGUMENT AND AUTHORITIES

A. Hospice Of New Mexico Has Standing To Assert This Claim

"When the suit is one challenging the legality of government action or inaction, the nature and extent of facts that must be averred (at the summary judgment stage) or proved (at the trial stage) in order to establish standing depends considerably upon whether the plaintiff is himself an object of the action (or forgone action) at issue. If he is, there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it." See Lujan v. Defenders of Wildlife, 504 U.S. 555, 561-562 (1992) (emphasis added).

Here, Hospice of New Mexico is challenging the legality of HHS' regulation, 42 C.F.R. § 418.309(b)(1). Hospice of New Mexico is undisputedly subject to the challenged regulation, in that HHS used the cap calculation method set forth in 42 C.F.R. § 418.309(b)(1) to calculate Hospice of New Mexico's cap repayment demand for FY 2006 and 2007. HHS calculated those repayment demands by allocating the entirety of each patient's cap room to a single year rather than allocating each patient's cap room across years of service, as Congress required. See 42 C.F.R. § 418.309(b)(1).

This resulted in cap repayment demands of $793,934 and $1,010,593 for FY 2006 and 2007, respectively. (UF 18, 21.) Again, it should be noted that Hospice of New Mexico has already repaid the FY 2006 demand; and, subject to this appeal, Hospice of New Mexico is currently paying the sum of $22,098.95 per month, inclusive of more than 11% interest toward the FY 2007 demand. (UF 18, 23.)

Here, Hospice of New Mexico is directly injured by the fact that HHS is using an invalid regulation, leading to accounting and payment inaccuracies. The harm to Hospice of New Mexico is certainly "actual," as Hospice of New Mexico has paid, and is paying (with interest), cap repayment demands calculated pursuant to the invalid regulation. In such circumstances, according to the Supreme Court, there is then "little question that [the regulation] has caused … injury, and that a judgment preventing [] the action will redress it." See Lujan, supra, 504 U.S. at 561-562.[3] These facts alone confer standing.

But Hospice of New Mexico has also offered further affirmative evidence of injury. First, the PRRB, a tribunal associated with HHS, has already determined that Hospice of New Mexico has standing to assert its claims to this Court, in that the PRRB found that the amount in controversy exceeds $10,000 – a finding which HHS did not object to or oppose. (UF 19, 22.)

Hospice of New Mexico has also demonstrated that: (a) HHS itself understood the prejudice and injury that would be caused by allocating cap room in only the first year of service; and (b) that HHS attempted to account for this prejudice by shifting the cap room for patients admitted within 35 days of the end of the fiscal year (i.e., between September 27 – and October

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[3] Moreover, Hospice of New Mexico need not demonstrate whether its liability would be greater under the operation of 42 C.F.R. § 418.309(b)(1) than it would be under some other regulation, because there is no other regulation. "This is always the circumstance when a party challenges an allegedly invalid regulation." (See order granting plaintiff's motion for summary judgment and denying defendant's motion for summary judgment in Los Angeles Haven Hospice case, attached to RJN at pp. 20-22 (Ex. 4.) Cf. Regents of the Univ. of Cal. v. Bakke, 438 U.S. 265, 280-281 n. 14 (1978) (rejecting argument that standing depended upon whether medical school applicant could show that he would have been admitted but for the challenged affirmative action admissions program); Village of Arlington Heights v. Metropolitan Housing Dev. Corp., 429 U.S. 252, 261-262 (1977) (holding that standing existed even though there was no guarantee that plaintiff would successfully obtain goal if requested relief were granted).

31) to the next fiscal year. HHS based its final regulation upon the assumption that the average length of stay in each hospice would be only 70 days (a number revised upwards in 1983 from HHS' previous estimate of 44 days).

The implicit assumptions in these shifts by HHS are twofold: (a) that to be fair to hospices, HHS would have to shift admissions forward into the next year in proportion to the length of stay; and (b) if the average length of stay was inaccurate, this would be prejudicial to hospices (thus causing HHS to revise its estimate from 44 days to 70 days, presumably to be more accurate).

But, by definition, the 35 day shift does not work for a hospice with a higher (or even lower) length of stay than 70 days. For a hospice with average length of stay longer than 70 days (like Hospice of New Mexico), under HHS' own assumptions, too much cap room will be allocated and trapped in prior years. (UF 13.) Cap allocations will not match revenue for these hospices, despite Congress' express intent to have allocations and revenue match. This problem is further aggravated by the fact that prior years have lower per patient allowances than later years, because the per patient allowance is adjusted annually for inflation. See 42 U.S.C. § 1395f(i)(2)(A).

Hospice of New Mexico has demonstrated that its average length of stay is longer than the HHS shift could account for. Specifically, Hospice of New Mexico's average length of stay over fiscal years 2006 and 2007 was 193 days. (UF 13.)

Moreover, the fact that hospices across 15 states (including New Mexico) have average lengths of stay in excess of 70 days demonstrates that the regulation is likely prejudicial not just to Hospice of New Mexico but to many hospices in New Mexico and across the country. (UF

12.) And, Hospice of New Mexico has offered evidence that in FY 2006 it continued to treat many patients first admitted in FY 2005, and that in FY 2007 it continued to treat many patients first admitted in FY 2005 and 2006. (UF 17, 20.)

In short, for any patient admitted prior to September 28, 2005 who continued to be treated by Hospice of New Mexico as of November 1, 2005, Hospice of New Mexico received no cap allocation to offset revenue in the subsequent cap year. Because Hospice of New Mexico has a length of stay longer than 70 days, the HHS shift by definition fails to push enough cap room from FY 2005 to FY 2006 and 2007. Thus, the injury to Hospice of New Mexico stems from HHS' failure to match cap allocations for certain patients with revenues paid to Hospice of New Mexico for treating those same patients.

For each of the reasons stated above, Hospice of New Mexico has demonstrated its standing to challenge 42 C.F.R. § 418.309(b)(1).

B. Under The *Chevron* Test, No Deference Is Given To Agency Action When Congress Has Spoken Directly To The Precise Question

In reviewing an agency's construction of a statute which it administers, there are two questions that must be answered: (a) "whether Congress has directly spoken to the precise question at issue;" and, (b) if not, "whether the agency's answer is based on a permissible construction of the statute." Chevron, U.S.A., Inc. v. NRDC, Inc, et al., 467 U.S. 837, 842-843 (1984). In answering the first question, no deference to the agency is due. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 512 (1996) ("where the language of the statute is clear, resort to the agency's interpretation is improper.").

Under Chevron, the first inquiry is "whether Congress has spoken directly to the precise question at issue." Chevron, supra, 467 U.S. at 842-843. Only if this question is answered in the

negative does a Court face the secondary question of whether the regulation is a reasonable interpretation of the statute. Id.

In making this first inquiry, whether Congress has directly spoken, no deference is due to agency actions. See Christensen v. Harris County, 529 U.S. 576, 588 (2000); Strickland v. Comm., Maine Dept. of Ag., et al., 96 F.3d 542 (1st Cir. Me. 1996). If the regulation conflicts with Congress' express mandate, then it must be invalidated. First Nat'l Bank of Milaca v. Heimann, 572 F.2d 1244, 1249 (8th Cir. 1978); see Wilcox v. Ives, 864 F.2d 915 (1st Cir. 1988) (regulation invalid where it was in "direct conflict with the plain meaning of the statute"; no deference appropriate unless agency's interpretation "is consistent with the language, purpose, and legislative history of the statute"). In this circumstance, the test is sometimes referred to as the "Chevron part 1 test," as only the first of Chevron's two questions is relevant to a determination of the regulation's validity. See Chevron, supra, 467 U.S. at 842-843.

As more fully described below, Congress has directly spoken on the issue in this case, requiring HHS to modify the "number of beneficiaries" in any given cap calculation "to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year." 42 U.S.C. § 1395f(i)(2)(C) (emphasis added). Because Congress has "spoken directly to the precise question at issue," the Chevron part 1 test applies, and HHS is not entitled to any deference in its interpretation of the statute.

C. The Hospice Cap Calculation Required By 42 C.F.R. §418.309(b)(1) Is Invalid Under *Chevron* Part One Because It Directly Conflicts With Section 1814 (i)(2)(C) Of The Medicare Act

In interpreting statutory texts, words should be given their ordinary meaning unless context requires a different result. Gonzales v. Carhart, 127 S.Ct. 1610, 167 L.Ed 2d 480 (2007).

Here, looking to the ordinary meaning of the Medicare Act, Congress has spoken to the specific question at issue – the allocation cap room for individual patients across years of service.

Since inception, the Medicare Act has provided that total payments to a hospice provider in any fiscal year may not exceed an aggregate cap, calculated as the product of the individual cap amount (adjusted annually for inflation) and the "number of Medicare beneficiaries" in a hospice program in an accounting year. The Medicare Act specifically provides that the number of beneficiaries in an accounting year must be adjusted to reflect the time each such individual was provided hospice care in a previous or subsequent accounting year. Specifically, Section 1395f(i)(2)(C) provides:

> "For the purposes of subparagraph (A), the 'number of Medicare beneficiaries' in a hospice program in an accounting year is equal to the number of individuals who have made an election under subsection (d) of this section with respect to the hospice program and have been provided hospice care by (or under arrangements made by) the hospice program under this part in the accounting year, such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year or under a plan of care established by another hospice program." (Emphasis added.)

(UF 3.)

In December 1983, and in spite of the foregoing statutory language, HHS issued its final hospice reimbursement regulation, including the provision allocating the hospice cap amount for a beneficiary only in the initial year in which the patient elected hospice care.[4] (UF 8.) The regulation provides:

> "Each hospice's cap amount is calculated by the intermediary by multiplying the adjusted cap amount determined in paragraph (a) of this section by the number of Medicare beneficiaries who elected to receive hospice care from that hospice

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4 "A regulation's age is no antidote to clear inconsistency with a statute." Brown v. Gardner, 513 U.S. 115, 122, 115 S.Ct. 552, 557 (1994).

during the cap period. For purposes of this calculation, the number of Medicare beneficiaries includes –

(1) Those Medicare beneficiaries who have not previously been included in the calculation of any hospice cap and who have filed an election to receive hospice care, in accordance with § 418.24 from the hospice during the period beginning on September 28 (35 days before the beginning of the cap period) and ending on September 27 (35 days before the end of the cap period).

(2) In the case in which a beneficiary has elected to receive care from more than one hospice, each hospice includes in its number of Medicare beneficiaries only that fraction which represent the portion of a patient's total stay in all hospices that was spent in that hospice. . . " (Emphasis added.)

(UF 8.) In fact, when HHS issued its proposed regulation to implement the hospice cap, it expressly acknowledged the statutory mandate to allocate each patient's cap allowance proportionally across years of service:

"The statute specifies that the number of Medicare patients used in the calculation is to be adjusted to reflect the portion of care provided in a previous or subsequent reporting year or in another hospice."

(UF 4.)

HHS nonetheless declined to adopt the specific computation methodology mandated by Congress, and instead chose to give providers credit for the cap only in the initial year of service, regardless whether the patient lived into another accounting year:

"With respect to the adjustment necessary to account for situations in which a beneficiary's election overlaps two accounting periods, we are proposing to count each beneficiary only in the reporting year in which the preponderance of the hospice care would be expected to be furnished rather than attempt to perform a proportional adjustment."

(UF 5.)

In so doing, HHS conceded that it was planning not to implement the plain language of the statute because it would be "difficult." HHS rationalized its decision thus:

> "Although section 1814(i)(2)(C) of the Act specifies that the cap amount is to be adjusted 'to reflect the proportion of the hospice care that each such individual was provided in a previous or subsequent accounting year . . .' such an adjustment would be difficult in that the proportion of the hospice stay occurring in any given year would not be known until the patient dies or exhausted his or her hospice benefits. We believe the proposed alternative[5] of counting the beneficiary in the reporting period where the beneficiary used most of the days of covered hospice care will achieve the intent of the statute without being burdensome." (Emphasis added.)

(UF 6.)

HHS may assert that compliance with the statute authorizing Medicare reimbursement for hospice care is "factually impossible." This assertion is demonstrably incorrect. Specifically, HHS abides Congress' mandate and apportions the cap between fiscal years when two hospices (rather than one hospice) provide care to a single patient:

> "We are aware that this type of apportioning of the beneficiary's stay may result in the inclusion of a beneficiary in the calculation of the cap for a reporting period other than the period for which the services were furnished, since it is necessary that the beneficiary die or exhaust his or her benefits before the percentage can be determined. However, we believe that this proposal is the most equitable means of implementing the statutory directive to adjust the cap amount to reflect the proportion of care furnished under a plan of care established by another hospice program." (Emphasis added.)

(UF 7.) In short, HHS has demonstrated through its own conduct that apportionment of the cap across years is indeed possible. Therefore, the wholly unsupported claim of "impossibility" is without merit. HHS makes the very same determination it claims is impossible in any case where a patient uses two hospices. If a single hospice provides care across two years, it should be entitled to the same calculation, the calculation mandated by Congress. Indeed, HHS'

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[5] In using the word "alternative," HHS acknowledged that it was departing from the express instruction of Congress when it established a rule by which each patient's total cap amount was allocated to a single year. In taking this step, HHS plainly chose to ignore Congress' express mandate.

assertion that it would be difficult to allocate cap room across years is legally irrelevant. See Ragsdale v. Wolverine World Wide, 535 U.S. 81, 89 (2002) (rejecting assertion that regulation should be upheld because it was easier to administer; holding that: "Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law'"; noting that: "By its nature, the remedy created by Congress requires the retrospective case-by-case examination the Secretary now seeks to eliminate").

Congress' express mandate regarding the calculation to be used in allocating the applicable cap, coupled with the fact that the HHS regulations blatantly ignore the Congressional requirement, should end the inquiry. Congress has directly spoken to the issue of the cap allocation, and the language of §42 C.F.R. § 418.309(b)(1) that is contrary to the mandate in the statutory provision should be held invalid.

Indeed, the court in Sojourn Care made the following findings on the record about the HHS regulation governing calculation of the cap (42 C.F.R. § 418.309(b)), before granting summary judgment that the regulation was invalid:

> "[W]ith due respect I agree with the plaintiffs here that the regulation as written does not comport or comply with the statute … I don't believe that the statutory language which requires that the number of Medicare beneficiaries is to be reduced is in any way reflected in an allocation to one of the fiscal years, one or the other, and it's certainly not – it doesn't honor the statutory language that the number must be reduced to reflect the proportion of hospice care that each such individual was provided … The number of Medicare beneficiaries is simply not reduced under this regulation in any way to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent reporting year … I simply don't believe that it follows the statutory mandate in the statute." (Emphasis added.)

(UF 24.) Similarly, the Los Angeles Haven Hospice court made the following findings before holding the same regulation invalid:

> "...Congress unquestionably required that the number of medicare beneficiaries be reduced to reflect 'the proportion' (not simply a proportion or an estimate, as Defendant [HHS] would apparently have 'reflect' mean in this context) of hospice care that 'each such individual' (not individuals in the aggregate) 'was provided in a previous or subsequent accounting year.' [Citations omitted.] The regulation in question runs counter to that directive. [Citations omitted.] Congress has 'directly spoken' to this precise question. [Citing Chevron, U.S.A., Inc. v. NRDC, Inc, et al., 467 U.S. 837, 842 (1984).] "That is the end of the matter." [Id.]

(UF 25.)

HHS' impermissible construction of the statute in the regulation is further highlighted by the fact that it made attempts to ameliorate the negative effects of its departure from Congress' mandate. Specifically, Medicare shifted the initial reporting year for "first election" of care from the standard Medicare fiscal year (November 1 through October 31) to an earlier time frame (September 28 to following September 27). Thus, if a patient was admitted on September 27, 2005, such patient's cap allocation would be included in its entirety to fiscal year 2005. However, if the same patient was admitted September 28, 2005, such patient's cap allocation would be entirely included in fiscal year 2006.

This shift, based on the assumption of an average stay of less than 70 days, is insufficient. As demonstrated by HHS changing its estimate of the average length of stay from 44 days to 70 days, if the average length of stay is inaccurate as to any hospice, it will produce incorrect and prejudicial cap repayment demands. But, in fact, HHS' estimate of 70 days is in fact inaccurate for many, many hospices.

Indeed, in calendar year 2005, 15 states (including New Mexico) had average lengths of stay in excess of 70 days. (UF 12.) Hospice of New Mexico's average length of stay across

fiscal years 2006 and 2007 was 193 days. (UF 13.) Therefore, under HHS' own assumptions, the cap repayment demand HHS issued to Hospice of New Mexico is inaccurate and prejudicial.

HHS' allocation of the cap amount only to the first reporting period in which the beneficiary elects the hospice benefit results in the assignment of the entire cap amount to the first reporting period even if most of the hospice care for that patient is rendered in a subsequent period. Thus, unused cap amounts in one fiscal year are "trapped" in the prior year. It is no surprise that in this case in its first year of operation, Hospice of New Mexico therefore had a cap surplus in excess of $700,000. (UF 16.)

The failure to allocate the cap across years of care is contrary to Congress' express mandate that the individual cap allowance be allocated proportionately across years of service. As a consequence, there is a costly mismatch of cap allocations and actual revenue, resulting in overstated repayment demands.

Here, Congress specifically required HHS to modify the "number of beneficiaries" in any given cap calculation "to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year." See 42 U.S.C. § 1395f(i)(2)(C) (emphasis added). Instead, HHS decided to only "count[] the beneficiary in the reporting period where the beneficiary used most of the days of covered hospice care." (UF 6.) Because Congress has "spoken directly to the precise question at issue," under the Chevron part 1 test, HHS is not permitted any deference in its interpretation of the statute. See Chevron, supra, 467 U.S. at 842-843. Under this standard, Hospice of New Mexico is entitled to summary judgment that 42 C.F.R. §418.309 is invalid because the regulation is in direct conflict with Congress' express mandate to perform proportional cap allocations.

V. PENDING FINAL JUDGMENT, HOSPICE OF NEW MEXICO REQUESTS A STAY OF REPAYMENT OF THE FY 2007 CAP DEMAND

As discussed above, Hospice of New Mexico has already paid in full the FY 2006 cap demand HHS issued to Hospice of New Mexico, this payment being without prejudice to the challenges contained herein. (UF 18.) However, on May 27, 2009, after Hospice of New Mexico filed its complaint in this matter, Medicare sent Hospice of New Mexico a demand for repayment of $1,010,593.00 for exceeding its FY 2007 cap. (UF 21.) Hospice of New Mexico has not fully repaid the FY 2007 demand but has instead applied for an extended repayment plan as to that amount and is currently paying the sum of $22,098.95 per month, inclusive of more than 11% interest, pending approval of the requested repayment plan. (UF 23.)

Pursuant to FED.R.CIV.P. 65, Hospice of New Mexico hereby requests that this Court enjoin and stay repayment/collection of Hospice of New Mexico's FY 2007 cap demand pending a final judgment in this matter, given Hospice of New Mexico's actual or likely success on the merits. See FED.R.CIV.P. 65; and order granting summary judgment (suspending FY 2006 repayment demand) and final judgment (setting aside FY 2006 repayment demand) in Los Angeles Haven Hospice, Inc. v. Michael O. Leavitt, Case No. 08-4469-GW (RZx) (C.D.Cal. filed 2008), attached to RJN as Exs. 4-5.

A stay of repayment of the FY 2007 cap repayment demand would prevent Hospice of New Mexico from suffering further harm (in the form of having to repay a significant cap demand that was calculated pursuant to a likely invalid regulation) pending final resolution of the issues raised herein, and would not unduly prejudice HHS in any way. Accordingly, Hospice of New Mexico respectfully requests that this Court enjoin and stay repayment/collection of Hospice of New Mexico's FY 2007 cap demand pending a final judgment in this matter.

VI. CONCLUSION

Because HHS' cap regulation fails to follow the statutory mandate to allocate each patient's cap allowance across years of service, Hospice of New Mexico respectfully requests that this Court grant summary judgment in its favor and against HHS, finding the cap regulation found at 42 C.F.R. § 418.309(b)(1) invalid. Pending such determination and/or pending final judgment (form to be determined), Hospice of New Mexico respectfully also requests that this Court stay HHS' FY 2007 repayment demand.

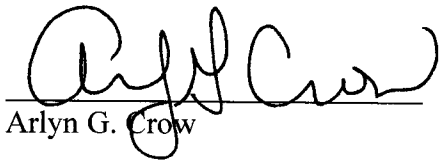
Dated: August 31, 2009

ARLYN G. CROW, P.C.
7500 Montgomery Boulevard, NE, Suite A
Albuquerque, New Mexico 87109
(505) 881-2782
arlyn@agcrow.com

BRIAN M. DAUCHER
(Pro Hac Vice Pending)
Sheppard, Mullin, Richter & Hampton LLP
650 Town Center Drive, 4th Floor
Costa Mesa, California 92626
(714) 424-2843
bdaucher@smrh.com

I HEREBY CERTIFY that on the 31st day of August, 2009, I filed the foregoing electronically through the CM/ECF system which caused the parties on the electronic service list to be served via electronic mail, and served the following via first class mail.

Manuel Lucero
US Attorney's Office
201 Third Street, NW, Ste. 900
Albuquerque, NM 87102

By: 
Arlyn G. Crow